



Bristol-Myers Squibb Company

Richard L. Wolgemuth, Ph.D.
Senior Vice President
Global Regulatory Sciences
Pharmaceutical Research Institute

P. O. Box 4000 Princeton, NJ 08543-4000
Tel 609-252-6503 Fax 609-252-7350
Richard.Wolgemuth@bms.com

July 9, 2004

Dockets Management Branch
Food and Drug Administration, HFA-305
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 2004N-0133; Electronic Record; Electronic Signatures; Public Meeting, Request for Comments [69 *Federal Register* 18591-18593 (April 8, 2004)]

Dear Sir or Madam:

Bristol-Myers Squibb (BMS), a diversified worldwide health and personal care company with principal businesses in pharmaceuticals, infant formulas, and nutritional products, is pleased to have the opportunity to offer comments on the electronic records and electronic signatures regulation. Our company's mission is to extend and enhance human life by providing the highest-quality pharmaceutical and related health care products. For this reason, we are interested in the FDA's initiative to re-examine the electronic records and electronic signatures regulation. Our comments are set forth below.

Summary of BMS Comments

We commend the U.S. FDA for its initiative in undertaking a re-examination of the Part 11 regulation and fully support this endeavor. Certain sections of the regulation are too prescriptive to allow for adopting newer technologies while others can be interpreted too broadly which has a tendency to unnecessarily increase compliance costs without added benefit. We encourage broad adoption of documented risk assessments to ensure that controls to safeguard records are appropriate and reasonable and are based on the potential of a system to affect product quality, patient safety, and record integrity. We believe such an approach would be a positive step toward promoting the widest use of electronic technology, compatible with FDA's mission to protect public health. We fully support the FDA's emphasis on maintaining or submitting records in accordance with the underlying predicate rules.

Specific Comments

A. Part 11 Subpart A – General Provisions

FDA requested comments on FDA's interpretation of the narrow scope of part 11 as discussed in the part 11 guidance and whether the part 11 regulation should be revised accordingly.

Comment: The part 11 guidance clarifies many ambiguities regarding what an electronic record is, and whether part 11 applies to those records.

Recommendation: Revise §11.1 and §11.2 to reflect the narrow scope described in the part 11 guidance.

Comment: The application of part 11 by the industry has been broadly interpreted such that any electronic record review or approval using an electronic signature capable computerized system requires application of an electronic signature. Revisions to the regulation should make it clear that electronic signatures being discussed by part 11 are only those signatures required by the predicate rule.

Recommendation: Revise §11.1 and §11.2 to reflect the narrow scope described in the part 11 guidance and enhance the guidance or definitions in the regulation to reflect the distinction between electronic signatures and part 11 signatures.

FDA requested comments on revisions to definitions.

Comment: Persons reading the definition of an "Electronic Record" may interpret that those are the

records to which part 11 applies. The part 11 guidance clarifies that part 11 applies to some, but not all, electronic records.

Recommendation: Add a definition for “Part 11 Records” consistent with the description in the part 11 guidance.

Comment: Persons reading the definition of an “Electronic Signature” may interpret that part 11 applies to all electronic signatures.

Recommendation: Add a definition for “Part 11 Signature” consistent with the description in the part 11 guidance.

FDA requested comments on the need for clarifying which records are required by predicate rule and therefore required to be part 11 compliant.

Comment: No clarification is required however additional definitions are suggested.

Recommendation: Include definitions as indicated above.

B. Part 11 Subpart B – Electronic Records

FDA requested comments on the need to distinguish between open and closed systems.

Comment: Underlying both §11.10 and §11.30 are requirements for security, confidentiality, the ability to maintain record content and integrity and individual accountability. The distinction between open and closed systems is unnecessary.

Recommendation: Remove the definitions of open and closed systems; re-title §11.10 to “Controls”; delete §11.30; add a new subsection to §11.10 as follows: “Additional measures such as document encryption and use of appropriate digital signature standards to ensure, as necessary under the circumstances, record authentication, integrity, and confidentiality.”

FDA requested comments on the need to retain the validation provision under §11.10(b).

Comment: We assume the notice should have referred to §11.10(a). This section is beneficial but could be enhanced by being less prescriptive in how to address accuracy and reliability of electronic records. The phrase “and the ability to discern invalid and altered records” has been the subject of a variety of interpretations and is only meaningful in the context of the system and associated electronic records.

Recommendation: Revise §11.10(a) to require controls necessary to ensure the accuracy and reliability of electronic records. Remove reference to the ability to discern invalid and altered records.

FDA requested comments on record copying requirements and preserving record security and integrity.

Comment: Strategies proposed in preamble and earlier “podium policy” were unclear and provided industry with little guidance concerning acceptable approaches and/or formats for archiving records and providing copies of e-records.

Recommendations: Revise §11.10(b) to be consistent with strategies provided in the part 11 guidance; clearly state that the organization owning data submitted to FDA or held in support of submitted data has responsibility for the creation, modification, maintenance, archival, retrieval, or transmittal of that data.

FDA requested comments on whether audit trail requirements should include safeguards to deter, prevent and document unauthorized record creation, modification and deletion.

Comment: Audit trail requirements should be based on documented risk assessments that address the sensitivity of records and their impact on product quality, patient safety and record integrity.

Recommendation: Revise §11.10 to reflect the approach to audit trails described in the part 11 guidance.

FDA requested comments on the need to revise §11.10(k) to incorporate concepts such as configuration and document management for all of a system’s software and hardware.

Comment: Introducing and defining configuration and document management concepts would be difficult. §11.10(k) is clear and concise as is.

Recommendation: Do not revise §11.10(k).

C. Part 11 Subpart C – Electronic Signatures

FDA requested comments on provisions of part 11 that should be augmented, modified, or deleted as a result of new technologies.

Comment: Controls to ensure security and integrity of records extends beyond those that are electronically

signed and §11.200 and §11.300 are too prescriptive and could limit use of new technologies. The regulation should be fashioned to be technology neutral.

Recommendation: Revise §11.200 and §11.300 and remove references to items related to how systems are implemented (e.g. identification codes, passwords, biometrics, etc.). Incorporate this information under Subpart B – Electronic Records. Communicate additional expectations through appropriate guidance documents.

BMS appreciates the opportunity to provide comment and respectfully requests that FDA give consideration to our recommendations. We would be pleased to provide additional pertinent information as may be requested.

Sincerely,

A handwritten signature in black ink, reading "Richard L. Wolgemuth". The signature is fluid and cursive, with a prominent initial "R" and a stylized "W".

Richard L. Wolgemuth, Ph.D.
Sr. Vice President, Global Regulatory Sciences